

**National Ethics Advisory Committee**

**26 May 2022**

**9:00am – 3:00pm**

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**Attendees**

**NEAC members:** Professor John McMillan (Chair), Shannon Hanrahan,
Dr Mary-Anne Woodnorth, Gordon Jackman, Dr Penny Haworth,
Associate Professor Vanessa Jordan, Dr Lindsey MacDonald, Rochelle Style, Edmond Carrucan, Dr Hansa Patel

**Apologies:** Dr Cindy Towns and Nora Parore

**Guests:** Manager of Ethics, Ministry of Health

Ministerial Advisor from the Office of the Minister of Health

 Principal Advisor, Public Health and Strategy and Advice, Ministry of Health

 Chair of the Southern Health and Disability Ethics Committee

# **Declaration of Interests**

1. Members updated the Committee and Secretariat with changes to their declarations of interests.

# **Actions**

* Secretariat to update members’ recorded declarations of interests.

# **Chair’s update**

1. The Chair raised that the COVID-19 regulations in NZ would allow for NEAC to meet in person. After discussion with the Committee, 22 September was set as a tentative date for a meeting to be held in person.
2. The Chair noted that they will be taking a 3-month overseas professorship and will not be available for NEAC meetings during this time. He raised that he would like to appoint a Deputy Chair to act on his behalf, noting the process outlined in the Terms of Reference (TOR) which will involve the Chair writing to the Associate Minister of Health for approval. The Chair confirmed that discussions with a member of NEAC had begun on appointing them as Deputy Chair.
3. It was noted that the Advisory Committee on Assisted Reproductive Technology (ACART) had recently appointed a Māori deputy Chair and updated their TOR to ensure that either the Chair or deputy Chair is Māori, and that NEAC is exploring a similar approach. A co-Chairing arrangement was also suggested. The Chair agreed and noted that this would need further discussion among the Māori representatives of NEAC.
4. The Chair raised that there are currently two working sub-groups on issues relating to NEAC and raised that newer members of NEAC are welcome to express interest and become involved. The Chair pointed specifically to the work around the Health Information Privacy Code 2020.
5. The Chair noted the TOR guidelines regarding confidentiality and discussing NEAC business outside of the Committee meetings. They particularly pointed to the ‘General meeting discussions’ section of the TOR, as found on the [HDEC website.](file:///C%3A%5CUsers%5Csmiles%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CWYN7L4RR%5C%E2%80%98https%3A%5Cneac.health.govt.nz%5Cabout-us%5Cterms-of-reference%5C#confidentiality)

## **Actions**

* The Secretariat will begin looking into travel logistics for a NEAC in-person meeting on 22 September 2022.
* NEAC members will discuss an interim Deputy Chair and formalising Māori governance in the TOR.

# **Approval of minutes from NEAC’s 24 March 2022 meeting**

1. The Chair noted the use of names throughout the minutes and requested that where possible to use the person’s role as an identifier rather than their name. The Secretariat agreed to do so unless the person’s name is specifically relevant to the update.
2. A NEAC member noted that an action point relating to point 62 in the minutes was missing from the final actions list. The section relates to the exclusion of disability-focused questions in the HDEC submission documents. The member requested that this be amended.
3. A NEAC member noted some of the language may not be lay-friendly and requested that more simple language is implemented where possible.

## **Actions**

* The Secretariat will remove names from the minutes.
* The Secretariat will ensure that the action point referred to above is added to the arising actions document. The Secretariat will discuss and liaise with the NEAC member and HDEC Chairs to ensure that there is sufficient representation in the HDEC screening documents.

# **NEAC Standards review**

1. A NEAC member involved in the Standards review subgroup presented an update to the Committee. The member discussed the subgroup's meeting the preceding week which focused on the health data chapter of the NEAC Standards. The member noted the content overlaps with many other chapters (e.g. emerging health technology and the quality improvement chapter).
2. The member explained it is important to keep the standards fit for purpose and noted the subgroup needs to be conscious of ensuring it captures any ethical or practical developments subsequent to the Standards publication in 2019 and cannot rely on public submissions alone.
3. The member discussed the Standards are constrained by a legally binding framework (including the Code of Health and Disability Consumers' Rights and Health Information Privacy Code) the subgroup must be mindful of.
4. The member discussed a public submission which detailed concerns around the standards of data storage in locked filing cabinets and whether this is truly secure. The member noted the Government has a 'cloud first' storage policy and queried whether a data security expert should be consulted.
5. The member noted that once tissue is analysed it becomes data and the subgroup would need to ensure there is no inconsistency between the data and tissue chapters.
6. Members discussed developments in Māori data sovereignty frameworks since 2019 the subgroup should consult and potentially incorporate or refer to in the chapter.
7. Members discussed the subgroup's request for a more formalised structure and timeline of the Standards review project. The Secretariat commented that this was in progress and an update would be provided to the subgroup shortly.

## **Actions**

* Secretariat to email NEAC members with formalised structure of Standards review project and to invite additional members into the project.

# **Research with adults who are unable to provide informed consent**

1. The Chair introduced this item and advised that he recently met with the Manager of Ethics and Secretariat to discuss next steps, noting that the Health and Disability Commissioner (the HDC) had not indicated her intentions regarding the former Commissioner’s report on this matter, since the Chair met with her on 10 November 2021.
2. The Manager of Ethics contacted the HDC twice prior to this NEAC meeting to request an update but had not received any response.
3. The Chair noted that at its meeting on 24 March 2022 NEAC considered a draft version of a detailed letter to the Minister of Health about this issue. However, the Chair proposed to members that the best approach is to write to the HDC requesting an update to clarify their intentions and any progress regarding the former Commissioner’s report. NEAC agreed with this approach.
4. NEAC may decide to write directly to the Minister of Health after hearing back from the HDC.
5. The Chair also referred to the Medical Research Institute of New Zealand’s Intensive Care Unit (ICU) matrix about approaches to potential scenarios for obtaining consent from incompetent participants after enrolment without prior written consent.
6. Members noted that there are inconsistencies in the ICU matrix and aspects of it do not reflect the current legal environment. Further, the relevant laws and regulations that might apply to the scenarios are not referenced.
7. Members discussed scenario six (participant dies before the study has been discussed with the family or other interested persons). It was noted that there are several legislative provisions which are inconsistent about whether they apply to deceased participants. Accordingly, the situation is more complex than what is stated for this scenario.
8. The ICU matrix also does not mention supported decision making. However, NEAC’s *National Ethical Standards for Health and Disability Research and Quality Improvement, 2019* and the Code of Health and Disability Services Consumers’ Rights are clear about the importance of supported decision making.
9. Members noted that if the ICU matrix can be finetuned and circulated to the HDC and ICU researchers, then this could assist significantly in resolving the issue of obtaining consent from incompetent participants after enrolment without prior written consent.
10. A member also noted that NEAC’s current work programme focuses on health and disability research. However, under the New Zealand Public Health and Disability Act 2000, NEAC must be responsible for the ethical standards across health and disability services, not just research. ICU and clinical ethics advisory groups are within NEAC’s scope and are particularly relevant in light of current pressures on the health system due to the COVID-19 pandemic. NEAC agreed to revisit the ICU matrix when considering its Decision-Making Framework.

## **Actions**

* Secretariat to work with the Chair to draft a letter to the HDC requesting an update on their intentions and any progress regarding the former Commissioner’s report
* NEAC to test the MRINZ ICU matrix through its Decision-Making Framework at its next meeting.

# **Wai 2575 – Health Services and Outcomes Inquiry**

1. Three members gave an update to the Committee regarding the findings of the Wai 2575 Health Services and Outcomes Inquiry, noting that they are thinking about this inquiry in relation to a presentation about indigenous populations in COVID-19 that they will be presenting at an upcoming WHO seminar.
2. The scope of the inquiry was to assess whether the Crown’s vaccination strategy and November 2021 COVID-19 protection framework had been consistent with Te Tiriti o Waitangi and its principles, as well considering what is needed to ensure the Crown’s vaccination strategy and protection framework are Te Tiriti compliant.
3. Some key issues emerged out of this inquiry:
	1. a lack of data collection around the vaccine rollout for Māori and disabled people (a failure of equity and protection).
	2. The Crown decided against advice from Māori health groups, data groups and its own officials around aged-based sequencing for the vaccine rollout, which noted that Māori have a significantly younger population. As a result, Māori were not positioned well under the COVID-19 Protection Framework, as it resulted in lower levels of vaccination amongst Māori.
	3. A lack of meaningful engagement with Māori and mahi tahi (partnership) around identifying how local assets and resources might be used, built up or deployed most effectively.
4. The inquiry showed that the Crown failed to act in a way that was consistent with the principles of Te Tiriti o Waitangi. Subsequently, the Minister of Health has accepted that partnership includes tino rangatiratanga in the Māori health system. Two further Te Tiriti o Waitangi principles have been added to the framework for how the health and disability system will meet its obligations under Te Tiriti in its day-to-day work:
	1. Equity – in health **outcomes** for Māori.
	2. Options - people get to **choose** between Māori-focussed and delivered health services and mainstream services.
5. The Pae Ora (Healthy Futures) Bill which creates Health New Zealand and Te Mana Hauora Māori (the Māori Health Authority) was discussed. This Bill has a section on Te Tiriti o Waitangi which intends to give effect to the principles of the Treaty and discusses working with Māori and delivering via Māori services. The government’s intention is to deliver a truly indigenous health system.
6. One member discussed reform via addressing the social determinants of health rather than directly through the health system, noting that the new policy framework for localities under the interim Māori Health Authority is intended to be wider than just health services. A new social sector commissioning framework was also noted.
7. Another member noted that NEAC’s previous advice around vaccine allocation had not been listened to and asked about NEAC’s role in making it public that their advice has been ignored.
8. A member suggested that NEAC could undertake an analysis of how well the Government’s response matched up to the advice that NEAC gave in their resource allocation guidelines and how NEAC, in hindsight, could have given their advice in a different way.
9. The Chair commented that para 36 of NEAC’s Terms of Reference gives room for NEAC to make comments to the media and that NEAC may wish to make more use of that.

# **Presentation and update to NEAC from Minister Little’s Office**

1. The overarching Kaupapa currently is the health reforms alongside the COVID-19 response, and both are likely to be priorities over the next year. Starting up two new authorities, Health New Zealand and Hauora Māori is in progress and the reforms provide NEAC, as a national committee, an opportunity to think about where it fits in the system and to work with Health New Zealand. Tier 1 priorities within the reform are: supporting the health workforce, delivering infrastructure (not only bricks and mortar facilities but including data and digital infrastructure), mental health and, underpinning all that we do rather than a singular priority, Māori and equity in the health system.
2. NEAC noted it has had a brief introduction into the legislation that will govern the health reform and noted that one of the Committee’s discussion points in regard to the reform has been around its functions of engagement and consultation and who it might approach at a national or local level to engage with on what it does. The advisor explained that as a default, agencies and local bodies are being asked to have an early conversation with Health New Zealand and Hauora Māori who are keen for discussion about their journey within the reforms. A proactive thing for NEAC to do is work with HNZ and Hauora Māori to understand day to day and how they work, and the Ministry is currently engaging with/reaching out to the Māori Health Authority.
3. A member also noted that from a community perspective it would be really helpful to see communication and engagement more planned. For example, it would be helpful for communities to have one place to go to where they can access information about where consultation is happening and what is going on. Some shared support and expertise could also be provided to scale up and coordinate to get best engagement with whanau and iwi.
4. The Minister is keen for sub agencies within the health sector to negotiate relationships on their own initiative with the key players in the health sector and be able to work out how they can add value. This is an initiative NEAC can take with the help of the secretariat and the Transition Unit to help find its place in the new system. The NEAC secretariat can look to set up regular schedule of the transition unit meeting NEAC.
5. A committee member noted some of the challenges in the data and digital space and that NEAC has some involvement in data and digital work through its Health and Disability Research ethical standards. The Ministerial Advisor noted that it is also a priority of the Prime Minister’s office to highlight what is being done this space in a way that respects privacy but also benefits health outcomes for New Zealanders and any work that NEAC can do in this space would be greatly appreciated. Data and digital conflicts are important on a national scale and the office would rely on the Ministry of Health to identify and monitor issues and report back so that the Minister can address them.
6. A member noted the equity lens across all that we do in the health system and noted that the COVID-19 pandemic has exposed weaknesses in the system for the disabled population. The Ministry for Disability appears to only deal with groups the state supports through disability services and does not cover all disabled groups. The member asked how information about equity with a disability lens is being included in the system. The advisor noted that the Minister’s expectation for Health New Zealand is that it will have disability voices and capability within itself and within the new Ministry for Disability. Work is being done on an incremental, sustainable basis to include the unique needs and aspirations of different groups and, on a day-to-day basis, not just for sweeping events like pandemics.
7. A member noted that one of the issues NEAC is thinking about in the context of its function of setting ethical standards for research in New Zealand is health workforce. Across New Zealand, one way the workforce is supported is through clinical advisory groups nested in DHBs. One of the things NEAC could consider is whether it could play a resourcing role in those groups. This is one way that NEAC could progress work at a national level that is feeding into workforce organised under a central agency. The advisor noted that as workforce is a priority for the Minister any work NEAC could do to support the workforce would be well-received. NEAC will prioritise feedback from the advisor about workforce into its framework.
8. A member asked whether there might be opportunity for a closer connection for work of NEAC with Minister through improved consultation between the Ministry and NEAC so that the Minister might get an advance on issues and ways of doing this were discussed. The advisor noted that he would be happy to progress this further in discussion with Ministry officials about how relationships might be strengthened.
9. The advisor noted that he would be interested to hear back from NEAC about how the new reform is working and how NEAC’s functions are fitting in to help show how the different bodies and committees are working together.

## **Actions**

* NEAC to consider the advisor’s feedback about workforce and data and digital and prioritise this in its decision-making framework.
* NEAC secretariat to look to set up a regular schedule of the Transition Unit meeting with NEAC.
* NEAC secretariat to meet with advisors from Minister Little’s office about how relationships might be improved.

# **Presentation to NEAC about health security and equity**

1. Health security is an international term used by WHO. The Interim Public Health Agency has been working collaboratively to determine what health security means for Aotearoa, New Zealand.
2. Internationally, the main global instrument for promoting health security is the International Health Regulations (IHR), which provide countries with the framework for what needs to be in place to prevent, respond and recover from pandemics.  The IHR monitoring and evaluation framework includes a joint external evaluation (JEE) and, in 2018 before the COVID-19 pandemic, Aotearoa New Zealand completed its first JEE in partnership with the WHO. Specific recommendations were agreed on how we could improve our health security.  As a result of the JEE, it was recognised that wider thinking about what health security means for Aotearoa NZ was needed rather than only responding to the technical aspects of the WHO tool.  For example, equity hardly featured in the tool. Work on framing health security in Aotearoa, NZ has been a staged journey so far and has included: a wānanga held in August 2021 with internal and external stakeholders on health security and Te Tiriti o Waitangi. A series of internal conversations on health security and equity that NEAC members have contributed to has also taken place along with work on what health security for various threats might look like. The discussions were very valuable in terms of broadening thinking.
3. Out of wānanga conversations a proposed definition for health security is that: Health security in Aotearoa is about protecting our people, communities and their whakapapa from threats to health and this is part of achieving Pae Ora.
4. Some of the other key points drawn from the wānanga conversations are that we need to strongly recognise the relationship between environment and health, listen to communities and particularly those who have been underserved by the system, to design a health system that works for all and that places people at the centre of the health and disability ecosystem and, embed kaitiakitanga and stewardship.  Health security needs to happen at a systems level and at a community level.
5. The strong messages were that embedding equity in health security requires: embedding relationships, effective communication and, quality data for all population groups (which the disabled community have strongly flagged with the Ministry) to plan and respond to threats we face.
6. The Committee noted it is mindful of the inequities with pandemics where social response is not embedded in planning and welcomes the Pae ora commissioning work and how it might link into the localities planning and how we join up social determinants of health thinking to improve the health of local populations.
7. The Committee noted the effects of COVID-19 and long COVID-19 are not yet known and in disabled communities there is talk of a “disability tsunami” that we won’t be equipped to cope with. This work on health security allows us to think in advance about the populations and communities in New Zealand and the kind of threats we might face and the things we can have in place based on learnings especially learnings from the COVID-19 pandemic.

## **Actions**

* Secretariat to share slides with NEAC for comment from members.
* Secretariat to facilitate further shared discussion between NEAC members and the Manatū Hauora staff working on health security

# **Framework for NEAC decision-making and prioritisation**

1. NEAC discussed its proposed Decision-Making Framework (the Framework), which had been updated by the Secretariat following discussion at NEAC’s meeting on 24 March 2022. The purpose of the Framework is to assist NEAC in deciding which items it should prioritise in its work programme.
2. Members provided minor feedback on the Framework for the Secretariat to action.
3. As raised earlier in the meeting, a member noted the importance of clarifying NEAC’s statutory functions and scope to make clear the distinction between research and practical ethics. She noted that the Framework currently only refers to research standards – NEAC’s *National Ethical Standards for Health and Disability Research and Quality Improvement, 2019*. However, NEAC is responsible not only for oversight of the Health and Disability Ethics Committees (HDECs), but also clinical ethics advisory groups in New Zealand that provide support and advice to health professionals on ethical issues arising from clinical practice or patient care.
4. The Chair also noted that NEAC’s Terms of Reference specifically refers to health and disability ‘services’ as well as ‘research’ with regards to its statutory functions.
5. A member also noted that the Health Research Council (HRC) is focused on health and disability research so there is some overlap of oversight from NEAC and the HRC; however, there is no overlap in terms of oversight of health and disability services. It was noted that NEAC should meet with the HRC to determine the level of overlap between NEAC and the HRC.
6. A member agreed and noted that, from a disability perspective, the lack of oversight of clinical ethics advisory groups has always been an issue due to the vast variance in delivery of health and disability services and ethics in delivery.
7. NEAC agreed to include ‘services’ in the Framework to clearly capture its scope.
8. NEAC tested the Framework by running two of its current work programme items through the Framework criteria. NEAC also discussed potential items that could be added to its work programme. It was agreed that members will individually test potential items through the Framework in their own time for discussion via an online poll tool at NEAC’s next meeting.
9. The Chair also gave a verbal update on an ICU triage model proposed by a DHB, which he has not received yet. Once received, this will be discussed at the next available NEAC meeting to determine how involved NEAC considers it should be in this matter.

## **Actions**

* Secretariat to action NEAC’s feedback on the Framework to further refine it
* Secretariat to circulate an Excel spreadsheet version of the Framework to members
* Secretariat to send members current and potential work programme items for them to test through the Framework in their own time for discussion at NEAC’s next meeting
* NEAC to finalise the Framework and agree on current and potential work programme items at NEAC’s next meeting
* Secretariat to arrange for representatives from the HRC to attend a future NEAC meeting.

# **Draft Ethical Guidance for a Pandemic**

1. The Secretariat updated the Committee on the work of the EGAP subgroup in getting the consultation communications plan ready and explained that the focus group composition was yet to be agreed.
2. The Secretariat advocated for focus groups to be comprised of individuals from within the same organisations in order to increase participant comfort to share their views on pandemic ethics. It was noted that participant organisations could be asked if there were other groups, individuals or organisations that they would like to pull into their focus group meeting, if they felt comfortable collaborating.
3. The Committee agreed this approach on principle, and the Secretariat noted that they will finalise the consultation documents. A further meeting of the EGAP subgroup was suggested before launching the consultation, though it was agreed that the consultation should launch as soon as possible.
4. It was confirmed that the consultation did not need to come back to the full Committee for approval before its launch.

## **Actions**

* Secretariat to confirm the consultation documents
* Secretariat to launch the consultation

# **Update from Chair of the Southern Health and Disability Ethics Committee**

1. The Chair of the Southern Health and Disability Ethics Committee (HDEC Chair) spoke to NEAC about the recent experiences of the HDECs.
2. The HDEC Chair presented data on the HDEC submissions received to date in 2022 that have received a final approval/decision. It was noted that the HDECs have already received a large number of applications this year.
3. The HDEC Chair also presented data on the average range turnaround time for the HDECs to process applications. Overall, the HDECs have been processing applications in accordance with timeframes; however, there have been a few outliers with some delayed in the full review pathway. The HDEC Chair explained that this was mostly due to sickness and availability of HDEC members, and researchers incorrectly submitting documents outside of the EthicsRM portal.
4. The HDEC Chair brought NEAC’s attention to some prevalent emerging issues in the HDECs space. These were:
	1. Researchers adapting study advertisements after approval, to emphasise the sum of reimbursement for study participation.
	2. Researchers citing multi-site organisational wide policy to use e-consenting for participants. Originally, this was only intended for observational studies involving adults and to combat disruptions to research caused by the COVID-19 pandemic. The HDEC Chairs had agreed in principle with the researchers’ intent; however, on review the HDECs have been receiving applications where it appears researchers have selected an e-consenting process without clear opportunities for individuals to speak one-on-one with a member of the research team.
	3. Recruitment of participants through general practitioners’ practices and primary care and the ethical consideration of how reimbursement on successful participant completion/placement affects the separation between the clinical team and researcher roles.
5. The HDEC Chair also outlined other recurring issues that the HDECs are noticing, such as:
	1. Over sampling
	2. Genetic/genomic future unspecified research
	3. Māori/Pasifika consultation
	4. Compensation for participant injuries – commercial versus Accident Compensation Corporation cover
	5. Multi-Country studies.
6. A member noted how the ethical issues relating to the HDECs are frequently recurring ones.
7. A member referred to the Standards review and asked the HDEC Chair what his perspective is on the Standards relevant to e-consenting, advertising, and recruitment, and whether those standards are sufficiently strong to cover some of the issues the HDECs have been experiencing. The HDEC Chair noted that the Standards are clear and are used by the HDECs to communicate when an application does not meet minimum ethical requirements. However, he noted that researchers have, on occasion, attempted to work around the wording of the Standards. He advised that he would raise this with the HDEC Chairs at their upcoming Chairs’ Day on 31 May 2022, and report back to NEAC.
8. A member raised that she had noticed that there is often significant use of branding on participant documentation, such as large sized and frequent use of pharmaceutical companies’ logos. She raised the concern that there might be subliminal influencing of participants, in relation to other products owned by the pharmaceutical companies. The HDEC Chair advised that he would also raise this at the upcoming Chairs’ Day.
9. A member asked if the HDECs have considered any applications for studies involving emerging health technology and if there is sufficient expertise on the HDECs for such a specialised area. The HDEC Chair advised that the Southern HDEC has seen only a few of these applications. He noted that this area is currently beyond the scope of his committee’s current member composition; however, as this is an emerging area, it is something to be aware of for future recruitment of HDEC members.
10. The Chair asked if the HDECs are seeing many applications relating to telehealth. The HDEC Chair advised that the HDECs have been receiving a few of these applications and this has prompted their discussions about e-consenting.

# **Correspondence**

## **Exclusion of access to ACC for participants in commercially sponsored clinical trials**

1. The Chair introduced this item, noting that there are revisions to the Accident Compensation Act 2001 (the AC Act) currently being considered through the Accident Compensation Corporation (ACC) Amendment Bill (the Bill).
2. The Secretariat revisited NEAC’s previous advice to the Minister of Health on this issue and drafted an updated letter about this issue.
3. NEAC agreed with the content of the draft letter and confirmed that it should be sent to the Minister of Health subject to additional content requested by members.

## **Actions**

* Secretariat to add content to the letter as requested by members and work with the Chair to finalise the letter before sending it to the Minister of Health.
* The Secretariat will update a stakeholder who has been in touch to inform them that NEAC has continued to discuss the issue and intends to write to the Minister.

# **Work between meetings**

1. NEAC discussed work between meetings. The Chair raised setting up a third working sub-committee which would focus on governance arrangements.
2. The Secretariat noted that NEAC members involved in sub-group and/or representing NEAC for presentations will be paid for their time.

## **Actions**

* Set up a third working sub-committee which would focus on governance arrangements.